In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-227V

(to be published)

* *	Chief Special Master Corcoran
ERIC LAPIERRE, *	
*	Filed: October 18, 2019
Petitioner, *	
*	Tdap vaccine; proof of injury;
v. *	small fiber sensory neuropathy;
*	weighing of expert opinions; ruling on
SECRETARY OF HEALTH AND *	the record
HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

Lauren Faga, Conway Homer, P.C., Boston, MA, for Petitioner.

Lynn C. Schlie, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On February 16, 2017, Eric LaPierre filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petitioner alleges that he experienced an unspecified peripheral neuropathy/polyneuropathy (most likely manifesting as small fiber sensory neuropathy) due to receipt of the tetanus-diphtheria-acellular pertussis ("Tdap") vaccine on June 11, 2014.

After the parties filed competing expert reports, and based on a preliminary view of the case file, I determined that the matter could be resolved by ruling on the record. To that end, the parties each filed briefs in support of their positions. Petitioner's Motion, dated February 25, 2019 (ECF No. 31)

[1] This Decision has been formally designated "to be published," and will be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

("Mot."); Respondent's Opposition, dated April 5, 2019 (ECF No. 33) ("Opp."); Petitioner's Reply, dated April 22, 2019 (ECF No. 35) ("Reply").

Having reviewed those filings, and as discussed in more detail below, I find that Petitioner has not carried his burden of proof. The record does not support Petitioner's contention that he experienced a small fiber sensory neuropathy (the diagnosis favored by his expert), and his symptoms were otherwise too nonspecific to link to any *other* defined vaccine injury, however characterized.

I. Factual Background – Medical Record

Vaccination and Initial Arm-Related Symptoms

On June 11, 2014, Petitioner (who was 35 years old at the time) presented to South Coast Medical Group ("SCMG") in Aliso Viejo, California, for evaluation of a three-month history of low back pain. Ex. 2 at 21. He was seen by a physician's assistant ("PA") and was prescribed ice, rest, over-the-counter pain relievers, and stretching exercises, and was referred for physical therapy ("PT"). *Id.* The same day, he also received the vaccination at issue: a Tdap vaccine in his left deltoid. *Id.* Petitioner claims that two days later, he felt severe pain at the injection site, and also noticed swelling under his arm. Ex. 18 (Aff. of Eric LaPierre) (ECF No. 8-1) at 1–2; Ex. 2 at 23.

Ten days later, Petitioner returned to SCMG on June 21, 2014. Ex. 2 at 22. He now reported swelling in his upper arm (purportedly beginning a few days after receiving the Tdap vaccine) along with swelling and discomfort in his axilla[3], and resulting in tingling from his upper arm to wrist. *Id*. However the examining physician (Eric Clark, M.D.) found no evidence of adenopathy[4] in either axilla, and there was no redness or swelling present either (although Petitioner claimed to be experiencing a swelling sensation in the right arm axilla as well). *Id*. at 23. Petitioner also displayed a full range of motion in both arms, with no decreased strength or sensation. *Id*.

Based upon examination—which as noted above was largely normal—Dr. Clark diagnosed Petitioner with transient bilateral axillary adenopathy of unknown etiology, adding that because Petitioner's symptoms had "occurred within one week after vaccine, Tdap, may be unusual reaction that seems to be self-limited." Ex. 2 at 23. Petitioner was also diagnosed with "[n]europathy-arm," and Dr. Clark allowed that this could be associated with the vaccination or "possible other cause such as transient [e]ntrapment." *Id*.

[3] "Axilla" is defined as: "the pyramidal region between the upper thoracic wall and the upper limb, its base formed by the skin and apex bounded by the approximation of the clavicle, coracoid process, and first rib; it contains axillary vessels, the brachial plexus of nerves, many lymph nodes and vessels, and loose adipose areolar tissue." *Dorland's Illustrated Medical Dictionary*, 185 (32d ed. 2011) (hereafter *Dorland's*).

[4] "Adenopathy" is defined as: "lymphadenopathy." *Dorland's* at 30. In turn, "lymphadenopathy" is defined as: "disease of the lymph nodes, usually with swelling; called also adenopathy. *Id.* at 1083 (emphasis in original).

Petitioner saw PA Kathryn Finch in follow-up at SCMG on June 26, 2014. Ex. 2 at 24. He now reported that the swelling in his right axilla had mostly resolved, but that he was still experiencing discomfort in the left axilla when he brought his arm down to his side, and was also noticing numbness and tingling in the medial aspect of his left arm. *Id*. On exam Petitioner displayed "possible mild tender lymphadenopathy palpable in left axilla" with no redness or edema, and had normal sensation, strength, and range of motion in his bilateral upper extremities. *Id*. at 25. In addition, blood testing came back normal. *Id.* at 30. PA Finch diagnosed him with lymphadenopathy of unclear etiology and paresthesias, prescribing medication for both. *Id*. at 25.

Petitioner returned to PA Finch a month later on July 23, 2014. Ex. 2 at 28. He reported dull, achy pain in his left armpit that was constant and aggravated when he pressed his arm against his side. *Id.* He also reported tingling down his left arm from the axilla to the wrist, and similar but less severe symptoms in his right arm, but no weakness or other upper body symptoms. *Id*. A physical examination was again normal, including upper extremity strength, sensation, and reflexes. *Id*. at 29. PA Finch diagnosed Petitioner with "Paresthesias/Axilla pain" and ordered x-rays of the cervical spine, which showed moderate disc space narrowing at the C6-7 levels of the cervical spine but without impingement on the spinal canal. *Id.* at 45. Lab testing (which included a comprehensive metabolic panel, TSH, sedimentation rate, vitamin B12, folate, C-reactive protein, and RPR (rapid plasma regain)) was all negative in its results. *Id*. at 31–32.

Continuation of Symptoms and Search for Cause

In the ensuing months, Petitioner's arm-related symptoms did not abate, leading him to seek more specialized medical treatment. To that end, on August 26, 2014, Petitioner saw neurologist Kenneth P. Martinez, M.D., at the Neurology and Pain Specialty Center in Aliso Viejo, complaining of pain in both axillae and tingling in his left arm that began three-to-four days after a Tdap vaccination in his left deltoid. Ex. 4 at 12. Despite his complaints, his exam was largely normal—his skin had normal coloration, texture, and moisture, he had no tenderness of his upper or lower extremities, and the initial neurological exam was also normal, revealing normal upper and lower extremity strength, sensation, and reflexes. *Id*. at 13–14. In addition, lab testing and autoimmune serologies produced normal/negative results. *Id*. at 28.

Nevertheless, Petitioner underwent bilateral upper extremity nerve conduction studies ("NCS"). *See generally* Ex. 4 at 22–24. Dr. Martinez interpreted the results as displaying "evidence for a mononeuropathy multiplex in bilateral arms (including the brachial plexus) s/p TDAP vaccine." *Id.* at 24. The identified affected nerves included a mild bilateral ulnar neuropathy at the elbow, mild bilateral ulnar neuropathy at the wrist, mild bilateral radial neuropathy at the wrist and forearm, mild bilateral digital neuropathy, and bilateral medial and lateral antebrachial cutaneous neuropathy in the forearms. *Id*. Based upon all of the foregoing, Dr. Martinez diagnosed Petitioner with a bilateral partial brachial plexus injury, and with bilateral mononeuropathy multiplex in both arms following Tdap vaccination. *Id*. at 14.

Petitioner returned to Dr. Martinez on October 7, 2014, complaining of fatigue plus worsening tingling and aching pain that had spread from his left arm to his right arm and both lower extremities. Ex. 4 at 5. Skin, musculoskeletal, and neurological exams remained normal and unchanged from previous visits. *Id*. at 6–7. The same day, another bilateral lower extremity NCS was performed. *Id.* at 21. Dr. Martinez interpreted the results as showing evidence of a "pure sensory demyelinating polyneuropathy" of the lower extremities. *Id.* Dr. Martinez now expanded his diagnosis, including with the August diagnosis (bilateral partial brachial plexus injury with mononeuropathy multiplex) a possible post-viral syndrome[5] with generalized myalgias and paresthesias, sensory demyelinating polyneuropathy, and possible multiple sclerosis as well. *Id*. at 7.

A few weeks later, on October 28, 2014, Petitioner saw a different neurologist, Theodore M. Teacher, M.D. Ex. 2 at 46. Dr. Teacher's examination (like those Petitioner had previously received) revealed normal bilateral extremity strength and sensation, normal bilateral grip strength, and normal reflexes, as well as brisk deep tendon reflexes in both knees. *Id*. Dr. Teacher concluded that Petitioner was not likely suffering from Guillain-Barré syndrome ("GBS"), a well-recognized peripheral neuropathy, but ordered an MRI to assess the presence of other possible demyelination or a neoplastic[6] process and recommended a rheumatology evaluation. *Id*.

In the meantime, Petitioner saw Dr. Martinez again on November 17, 2014, complaining of fatigue plus worsening numbness, tingling, and aching pain, which he represented now affected all four extremities as well as his face. Ex. 4 at 1. Musculoskeletal and neurological exams were normal and unchanged from previous visits. *Id*. at 2–3. Bilateral upper extremity NCS testing was performed again, and Dr. Martinez interpreted the results as showing evidence of a mild-to-moderate left ulnar neuropathy at the elbow, but not supporting a bilateral brachial plexopathy, right ulnar neuropathy, or polyneuropathy affecting the upper extremities. *Id*. at 18. Based on this exam, Dr. Martinez assessed Petitioner as having experienced a "pure sensory polyneuropathy of both arms and legs," which was "[l]ikely secondary to auto immune phenomenon triggered by Tdap vaccine given time of onset," but had "improved in the upper extremities based on today's study." *Id*. at 3. Petitioner chose not to take gabapentin or receive IVIG therapy in treatment of his symptoms. *Id*.

On December 1, 2014, the results of the MRIs of the cervical spine, brain, and left brachial plexus previously ordered by Dr. Teacher came back as normal. Ex. 5 at 22–24. A PT evaluation Petitioner subsequently received on December 4, 2014, noted "mild right shoulder/rotator cuff weakness from years of playing volleyball," and noted Petitioner's left shoulder and elbow pain since having the Tdap vaccine almost six months before. Ex. 9 at 23. On December 29, 2014, Petitioner followed up with Dr. Teacher, whose diagnosis now centered on attempting to rule out fibromyalgia. Ex. 5 at 22. Petitioner

[5] Lab testing for Parvovirus B19 showed an elevated IgG and normal IgM indicative of past Parvovirus infection. Ex. 2 at 25.

[6] "Neoplastic is defined as "pertaining to or like a neoplasm." *Dorland's* at 1239. "Neoplasm" is defined as "any new and abnormal growth; specifically a new growth of tissue in which the growth is uncontrolled and progressive []. Malignant Neoplasms are distinguished from benign in that the former show a greater degree of anaplasia and have the properties of invasion or metastasis. Called also tumor." *Id.* (emphasis in original).

also began obtaining treatment from a chiropractor, although he only stayed with it through mid-January 2015. Ex. 6 at 14–35.

2015 Treatment

In late January 2015, Petitioner began seeing a rheumatologist, David Kovacs, M.D. Ex. 7 at 8. Once again, Petitioner's physical exam was largely normal, except for evidence of pain with right shoulder abduction from 60 to 120 degrees. *Id.* at 9–10. Dr. Kovacs's evaluation from January 29, 2015, noted that Petitioner had "no past medical history" consistent with his current symptoms, which he primarily characterized as "worsening pain in his right shoulder with [a]bduction from 60-120 [which] may suggest a component rotator cuff outlet impingement," although "the etiology of his numbness and tingling at this point are likely not related to his complaints of joint [symptoms]." *Id.* at 10. Dr. Kovacs also observed the lack of evidence of any underlying immunologic source for his symptoms based on "extensive" lab testing and the absence of biomarkers suggestive of inflammation. *Id.* Based upon a physical exam and an extensive immunologic workup, Dr. Kovacs's initial differential diagnosis included myalgia, arthralgia, and vitamin D insufficiency. *Id.*

Dr. Kovacs subsequently ordered a wide array of lab tests, all of which (consistent with previous similar testing) produced normal results. Ex. 7 at 11–19.[7] X-rays of Petitioner's shoulders, however, revealed mild degenerative changes of the left acromioclavicular ("AC") joint and down-sloping of the right acromion "with suggestion of outlet impingement." Ex. 13 at 1, 10. In addition, x-rays of the sacroiliac joints showed mild sclerosis suggestive of possible sacroiliitis but without erosive changes. *Id*. at 13. On February 12, 2015, after review of the lab work and x-ray results, Dr. Kovacs noted that a spondyloarthropathy[8] could be a unifying diagnosis, but felt it unlikely because Petitioner was HLA-B27 negative[9], had no acute inflammatory markers, and an atypical history otherwise. Ex. 7 at 8. Dr. Kovacs also noted that any right shoulder pain Petitioner had previously experienced was probably attributable to subacromial bursitis. *Id*. At most, the sclerosis evident in Petitioner's bilateral sacroiliac joints suggested the possibility of sacroiliitis. *Id*. at 6, 7. Dr. Kovacs did not otherwise propose (as had been suggested in the summer of 2014 by other treaters) that Petitioner's ongoing symptoms could be attributed to vaccination.

[7] Testing specifically included serum and urine protein electrophoresis, creatinine kinase, HLA-B27, celiac panel, C-reactive protein, CCP antibody, and hepatitis B/C serologies. Ex. 7 at 11–19.

[8] "Spondyloarthropathy" is defined as: "disease of the joints of the spine." *Dorland's* at 1754 (32d ed. 2011). It refers to a family of degenerative inflammatory joint disorders, include ankylosing spondylitis (AS), reactive arthritis, and psoriatic arthritis. *See Fraser v. Sec'y of Health & Human Servs.*, No. 17-1229V, 2019 WL 4741745, at *2 n.2 (Fed. Cl. Spec. Mstr. Aug. 9, 2019) (citing *Dorland's*).

[9] Spondyloarthropathies are strongly associated with the HLA-B27 biomarker. *See Fraser*, 2019 WL 4741745, at *2 n.2 ("[t]he HLA-B27 biomarker is present in about 80–95% of patients with ankylosing spondylitis"); *Godfrey v. Sec'y of Health & Human Servs.*, No. 10-565V, 2015 WL 10710961, at *2–3 (Fed. Cl. Spec. Mstr. Oct. 27, 2015), *mot. for review denied*, slip op., Apr. 29, 2016 (ECF No. 109). While not diagnostic alone, a positive test for HLA-B27 is a strong indicator of a spondyloarthropathy. *See Fraser*, 2019 WL 4741745, at *2 n.2.

On March 4, 2015, Petitioner received a right shoulder MRI that showed moderate degenerative changes of the AC joint and changes consistent with outlet impingement, as well as also a low grade partial-thickness tear of the rotator cuff, mild adhesive capsulitis, and tenosynovitis of the biceps tendon. Ex. 7 at 22. However, an MRI of his pelvis performed on the same day showed no evidence of sacroiliitis. *Id*. at 26. At a follow-up visit on March 12, 2015, Dr. Kovacs now opined that Petitioner "may have a component of fibromyalgia/chronic pain [which] is contributing to his symptoms." *Id*. at 4. However, Dr. Kovacs repeated that he had found no evidence of an underlying autoimmune condition, and he therefore recommended an orthopedic evaluation for petitioner's right shoulder. *Id*.

Petitioner subsequently saw an orthopedist, Warren G. Kramer, III, M.D., on March 31, 2015, and was treated with a steroid injection into his right shoulder. Ex. 8 at 14, 17–18. At the time of this examination, Petitioner noted that he was currently able to engage in some athletic activity, like volleyball, but that he had otherwise limited his activity due to ongoing symptoms. *Id*. at 14. He was prescribed PT for both his left and right shoulder. *Id*. at 18–19. Thereafter, in the next several months, Petitioner saw Dr. Kramer on a few additional occasions and underwent further imaging of his right shoulder. *Id*. at 5–13. By June, Dr. Kramer had diagnosed Petitioner with a superior labrum anterior to posterior ("SLAP") tear and a partial supraspinatus tear in his right shoulder, and recommended arthroscopic surgery. *Id*. at 1–4.

On August 31, 2015, Mr. LaPierre saw Tiyonnoh M. Cash, M.D., a neurologist and neuromuscular specialist at University of California Irvine Health ("UC-Irvine"), for "evaluation of paresthesias and pain following vaccination in 2014." Ex. 12 at 1. Consistent with the record from prior medical visits, Petitioner reiterated his reports of left axillary swelling two-to-three days after vaccination, along with paresthesias distal to his shoulder, adding that both were resolving but had left a dull, achy pain in his axilla and ongoing dull pain in his left arm, lower back, elbow and hands. *Id*. Petitioner also reported the limitations on his activity and lifestyle that his symptoms had forced upon him. *Id*. at 2.

Dr. Cash's exam of Petitioner revealed 5/5 strength, increased deep tendon reflexes (3+) in the arms, and normal reflexes (2+) in the legs. Ex. 12 at 4. Sensory testing, coordination, and gait were also all normal. *Id*. In response to Petitioner's request, Dr. Cash ordered urine heavy metal testing, which was negative. *Id.* at 5, 12. In addition, an EMG of both legs and the left arm, taken on October 2, 2015, also showed no evidence of a left cervical or lumbosacral radiculopathy, entrapment mononeuropathy, generalized sensorimotor polyneuropathy, or myopathy. *Id*. at 9. Furthermore, NCS testing performed the same day as the EMG was also normal. *Id.* at 8. Dr. Cash opined that brachial plexitis and mononeuritis multiplex were unlikely causes of Petitioner's symptoms, and also deemed an onset of two-to-three days after vaccination to be "too acute" for an autoimmune condition. *Id*. at 4. He further noted that Petitioner's increased reflexes with normal motor and sensory exams might be consistent with cervical/ lumbosacral radiculopathies vs. myelopathy vs. anxiousness. *Id.*

At a follow-up visit to Dr. Cash on October 7, 2015, a neurology resident noted in a medical record that EMG/NCS testing had ruled out a brachial plexopathy and mononeuritis multiplex, making

it impossible to attribute Petitioner's symptoms to "a nerve/muscle disease," but leaving the possibility of "a pain syndrome related to vaccine or other factors." Ex. 12 at 8. Dr. Cash proposed that Petitioner's symptoms were likely musculoskeletal, and deemed further neurologic work-up unwarranted. *Id*.

More Recent Medical History

From October 2015 to January 2017 (the month prior to this action's filing), Mr. LaPierre's ongoing treatment seems to have largely been obtained from alternative care providers. *See generally* Exs. 11, 16, 17, 23, and 24. One treater's diagnosis (from June 2, 2016) included complex regional pain syndrome ("CRPS") after a Tdap vaccination and chronic fatigue. Ex. 16 at 1. Another treater, Dr. Wade Binley (the chiropractor Petitioner began seeing in 2016), noted diagnoses of "neuropathy caused from Tdap," auto-immune phenomenon, post-vaccine neuralgias, causalgia (aka CRPS), fibromyalgia, possibly mitochondrial defect, upper extremity peripheral neuropathy, myositis, and lumbar pain. Ex. 17 at 5; Ex. 23 at 1–3. And a third treater recorded that Petitioner had experienced adverse reaction to vaccine, paresthesias of the arm, low back pain, headache, neck pain, chronic pain, nutritional deficiency, and fatigue. *See generally* Ex. 24.

II. Expert Reports

A. *Petitioner's Expert - Dr. Thomas Morgan*

Petitioner submitted two expert reports from Thomas Morgan, M.D., a neurologist and independent medical examiner. Report, dated December 18, 2017, filed as Ex. 27 (ECF No. 20-1) ("First Morgan Rep."); Report, dated September 14, 2018, filed as Ex. 29 (ECF No. 26-1) ("Second Morgan Rep.").

Dr. Morgan graduated from Meharry Medical College in 1970 (after completing his undergraduate degree at St. Louis University). Ex. 28 at 1. Dr. Morgan went on to complete his residencies in internal medicine at Brown University School of Medicine (1970–1972) and neurology at Boston University School of Medicine (1972–1975). *Id*. at 2. Dr. Morgan is board certified in psychiatry, neurology, and as a medical examiner. *Id.* at 3. He is currently with the Department of Clinical Neuroscience at Brown University as a clinical assistant professor and maintains a clinical practice at a private office as a disability examiner. *Id*. at 4.

First Report

In his initial expert report, Dr. Morgan included a detailed overview of Petitioner's medical history as discussed above. He directly opined that Petitioner has a "sensory variant of Guillain-Barré Syndrome . . . specifically a sensory neuropathy syndrome of the small fiber type." First Morgan Rep. at 8. He based this conclusion on the record evidence of EMG and NCS studies (largely obtained by Dr. Martinez in the fall of 2014), acknowledging that although the results from such testing were not corroborated by later follow-up studies, Petitioner had continued to experience sensory symptoms. *Id.* at

7. He also noted that it was not in his experience uncommon for "residual neurological complaints" attributable to a small fiber neuropathy to exist even though testing revealed otherwise normal results. *Id.* However, he directly disputed the suggestion (set forth in part in the more recent medical record) that Mr. LaPierre had CRPS, arguing that the diagnostic criteria for that condition had not been met. *Id.* at 8.

To explain how the Tdap vaccine could precipitate a sensory small fiber neuropathy, Dr. Morgan implicated molecular mimicry—the same mechanism believed to be responsible for causing post-vaccinal GBS generally. First Morgan Rep. at 7–8. Specifically, he proposed that the protein antigens presented by this vaccine were similar (in structure or amino acid sequence) to protein components found in the thinly-myelinated or unmyelinated small sensory nerve fibers, thus resulting in a cross-reaction when antibodies produced in response to the vaccine also attacked the mimic self structures. *Id.* at 8. He also opined that the timeframe in which Petitioner began experiencing symptoms—the arm swelling beginning a few days after vaccination, followed by neurologic symptoms—was medically acceptable. *Id.* at 8.

Dr. Morgan did not offer literature directly establishing such contentions, although (along with some general textbook excerpts) he filed one article raising the question of whether small fiber sensory neuropathies in fact constitute a GBS variant. *See* U. Seneviratne, et al., *Acute Small Fibre Sensory Neuropathy: Another Variant of Guillaine-Barré syndrome?* 72 J. Neurol. Neurosurg. Psych. 540–42 (2002) (ECF No. 20-1 at 23–25)[10] ("Seneviratne"). Seneviratne discusses six case report instances in which the article's authors encountered patients presenting with acute onset peripheral sensory neuropathy (primarily numbness and sensory loss in both the upper and lower limbs) but normal reflexes, no ataxia or cerebellar dysfunction, and no evidence of demyelination. *Id.* at 540–41. Two of the patients experienced complete recovery in two weeks, while the remaining four continued to experience symptoms for many months, recovering), from presenting pain or subjective sensory loss sooner than objective loss. *Id.* at 541. Seneviratne proposed that the observed case studies met proposed criteria for a sensory form of GBS (that would involve sensory nerves and not feature areflexia or demyelination, and (as its authors stated) the results of such studies "hints" that small sensory nerves could be autoantibody targets in the same way GBS is believed to develop—although the article did not specifically evaluate this possibility, and indicated that additional research would be required to confirm it. *Id.* at 542.

Second Report

Dr. Morgan's second report responded directly to the contentions of Respondent's expert (as described below). He agreed that the medical record did not support the conclusion that Petitioner had experienced "classic" brachial plexopathy, and also that Petitioner's symptoms could not completely satisfy the accepted criteria for GBS. Second Morgan Rep. at 2, 3. But he nevertheless expressed confidence in the small fiber sensory neuropathy diagnosis, explaining away inconsistencies or contradictory evidence.

[10] Exhibits to Dr. Morgan's first report were filed as a continuous sequence with his report, rather than as separate pdf files.

Thus, Dr. Morgan did not find it significant that Petitioner could not establish the existence of many of the criteria for GBS. Even though Mr. LaPierre's presentation was not monophasic, for example, Dr. Morgan felt that the persistence of his symptoms was consistent with the kind of sequelae *other* GBS patients experienced even after the disease had mostly dissipated. Second Morgan Rep. at 2. As a GBS variant, on a "spectrum" of GBS from mild to severe, Dr. Morgan seemed unsurprised by Petitioner's overall course and timeframe, as well as the fact that many criteria for GBS were unquestionably unsatisfied. *Id.* at 3. He also did not accept the characterization of his opinion as proposing that Petitioner's GBS had "evolved" into something different, maintaining that in fact all he suggested was that Petitioner had experienced a GBS variant *overall*. *Id.* at 3, 4.

Dr. Morgan allowed that the small fiber neuropathy diagnosis he was proposing lacked the support of a skin biopsy, and that such a test was a significant element of any small fiber neuropathy diagnosis. Second Morgan Rep. at 4. But Dr. Morgan felt that clinical evidence of the condition was equally important, and present in this case. *Id.* He also deemed highly significant Dr. Martinez's positive NCS results—although they were not (at least when initially rendered) cited by Dr. Martinez to support a small fiber neuropathy diagnosis, and Dr. Morgan seemed to accept Respondent's expert opinion that NCS testing did not bear on a small fiber neuropathy diagnosis in any event. *Id.* Dr. Morgan went on to highlight Dr. Martinez's views, reflected from the medical records, that Petitioner's condition was most likely autoimmune in origin. Second Morgan Rep. at 5.

To bulwark arguments set down in his first report, Dr. Morgan offered some additional literature. Some items expanded slightly on Seneviratne's speculation that small fiber sensory neuropathy might constitute a GBS variant. *See, e.g.*, A. Binder, et al., *Size Matters – Small Fiber Neuropathy in the Guillain-Barré syndrome*, 151 Pain 9–10 (2010), filed as Ex. 29, Tab A (ECF No. 26-2) (commenting on the possibility that small fiber neuropathies might represent a chronic secondary effect of the biologic demyelinating processes understood to cause GBS); V. Martinez, et al., *Small Fibre Impairment Predicts Neuropathic Pain in Guillain-Barré syndrome,* 151 Pain 53–60 (2010), filed as Ex. 29, Tab B. But such articles largely seemed focused on explaining chronic pain in individuals who unquestionably had *first* experienced GBS, with less discussion of small fiber neuropathies alone occurring in the absence of GBS. He also referenced a section from the Institute of Medicine's publication pertaining to adverse vaccine events, although it addresses GBS only. *Adverse Events Associated with Childhood Vaccines* 44–47 (K. Stratton, et al., eds., 1994), filed as Ex. 29, Tab E (ECF No. 26-6).

B. *Respondent's Expert – Dr. Jeffrey Cohen*

Dr. Cohen filed a single report in this action. *See* Report, dated April 7, 2018, filed as Ex. A (ECF No. 23-1) ("Cohen Rep.").

Dr. Cohen completed his undergraduate degree at Tulane University, which he attended from 1969 to 1973. Ex. B at 1. During this period he studied aboard at the University of Glasgow from 1971 to 1972. *Id.* Later he graduated from the University of Oklahoma College of Medicine in 1977. Then he

completed his residencies in Neurology at Mount Sinai Hospital, New York, New York. *Id.* (1977–1981). Thereafter he went on to complete two fellowships: First, a clinical and research fellowship in Neurology with experience in Neuromuscular Disease and Neurophysiology at Massachusetts General Hospital in Boston (1981–1982); second, a fellowship in Peripheral Nerve Disease, with experience in clinical and pathologic aspects of nerve disease, at the Mayo Clinic in Rochester, Minnesota (1985–1986). *Id.* Dr. Cohen is board certified in neurology, psychiatry, clinical neurophysiology, neuromuscular disease, neurorehabilitation, eltrodiagnostic medicine, and pain management. *Id.* at 1–2. He is currently the chairman of neurology at Dartmouth Medical School and sees patients Dartmouth-Hitchcock Medical Center. *Id.* at 2.

Dr. Cohen's review of Mr. LaPierre's medical records produced a conclusion contrary to that of Dr. Morgan. Noting the "changing diagnoses" evident from that overall record, he discerned Dr. Morgan's opinion to be that Petitioner presented with "bibrachial plexopathy," evolving into a GBS sensory variant that was ultimately best characterized as a small fiber neuropathy. Cohen Rep. at 1. Dr. Cohen's view was that *none* of these diagnoses were correct, whether viewed as related or separately. *Id.* at 2–5.

First, Dr. Cohen rejected the conclusion that Petitioner had experienced a brachial plexopathy or GBS as it is most commonly understood.[11] Regarding the former, Dr. Cohen opined that both NCS and EMG studies would be required to confirm the diagnosis, but in Petitioner's case only NCS studies were performed by Dr. Martinez—and those studies were not later confirmed in 2015 by UC-Irvine when they were repeated, while the EMG performed for the first time was normal. Dr. Cohen felt neither of these test results would have come back normal had Petitioner in fact experienced a brachial plexopathy. Cohen Rep. at 2. He also rejected the validity of a GBS diagnosis, observing that if the proper criteria were considered[12], Petitioner's symptoms met none, although they particularly did not reveal an acute onset, monophasic course, areflexia, or lab results confirming the presence of inflammatory demyelinating processes in the cerebrospinal fluid. *Id.* at 3–4.

Second, Dr. Cohen expressed doubt that Petitioner had experienced a small fiber neuropathy of any kind, let alone one reflecting a sensory GBS variant. He noted that Petitioner had never been so diagnosed in the course of his treatment, never displayed what Dr. Cohen deemed the common relevant symptoms (distal feet/hands symmetrical pain coupled with loss of pain or temperature sensation), and did not even have a skin biopsy to confirm the diagnosis (a test he deemed the "gold standard" for identifying small fiber neuropathy). Cohen Rep. at 4. He also doubted that an individual's symptoms

[11] In the Vaccine Program, the "AIDP" variant of GBS (standing for acute inflammatory demyelinating polyneuropathy) is the most common form of the peripheral neuropathy. *See Braun v. Sec'y of Health & Human Servs.*, No. 16-1098V, 2018 WL 2375751, at *7 n.9 (Fed. Cl. Spec. Mstr. Apr. 24, 2018) (AIDP accounts for 85–90% of GBS cases in the United States).

[12] The "Brighton Criteria" are the established criteria for GBS diagnosis. *See Harrington v. Sec'y of Health & Human Servs.*, No. 15-752V, 2018 WL 1125831, at *5 (Fed. Cl. Spec. Mstr. Jan. 19, 2018) (analyzing Dr. Cohen expert report concerning GBS diagnosis in previous case).

course would progress in the manner Mr. LaPierre's had, evolving from Dr. Martinez's initial diagnosis of brachial plexopathy into a small fiber neuropathy. *Id.* And he questioned whether Petitioner's symptoms could be characterized as *any* GBS variant, when they could not meet the primary criteria for GBS in the first place (and given that Petitioner complained of weakness—a symptom not associated with sensory-variant GBS in Dr.Cohen's opinion). *Id.*

Dr. Cohen also considered the literature offered in support of Dr. Morgan's opinion, observing that it reflected either general understanding about GBS (and hence did not undercut his points) or confirmed the need for additional testing to establish that Petitioner in fact suffered from a small fiber sensory neuropathy. Cohen Rep. at 5. He specifically observed that Seneviratne was inapposite, since the GBS of the six case study patients had been confirmed with a spinal tap (testing that was never performed on Petitioner), and that its "clinical relevance" as a potential diagnosis was otherwise questioned by "most neuromuscular specialists." *Id.* Finally, he emphasized that Dr. Morgan's mechanism arguments involving molecular mimicry as the pathogenic engine for sensory small fiber neuropathy/GBS variant were unsupported by reliable evidence. *Id.*

III. Procedural History

As noted, Petitioner's claim was initiated in February 2017. After obtaining and submitting medical records relevant to the matter, the parties filed a joint statement of completion on May 16, 2017 (ECF No. 11), with Respondent's Rule 4(c) Report following in July (ECF No. 14). Dr. Morgan's first expert report was thereafter submitted in December 2017 (ECF No. 20), prompting a responsive report from Dr. Cohen in April 2018 (ECF No. 23). Petitioner filed a supplemental report from Dr. Morgan in September 2018, and the following month I proposed resolution of the case via ruling on the record and set an initial briefing schedule (Docket Order, dated October 18, 2018). After some delays, both parties completed filing of their respective briefs by April 2019, and the matter is now ripe for resolution.

IV. Parties' Respective Positions

Petitioner's Argument

Following a detailed review of the medical history, Petitioner makes a number of arguments in his motion for ruling on the record to support a favorable entitlement award. First—and somewhat inconsistently with Dr. Morgan's opinion—Petitioner proposes that his injury is best characterized as a general "peripheral neuropathy." Mot. at 32. In so arguing, he notes the distinction between establishing a *diagnosis* (which he purports is unnecessary in Vaccine Act cases, and in any event is a task beyond the special master's purview) and vaccine *injury*, underscoring that the latter can be established even if the exact or proper characterization of that injury cannot. *Id.* at 32–34, 41 ("[p]recise categorization of [Petitioner's] injury is not necessary to his claim's success"). And he maintains that Dr. Morgan's opinion is deserving of weight given his individual expertise. *Id.* at 41–42.

Second, and based on the above (while recapitulating aspects of the medical record), Petitioner argues that his injury (now calling it a "polyneuropathy") evolved over time, reading Dr. Morgan's

opinion of injury as supportive (although as noted above the best reading of those opinions is that Dr. Morgan favors small fiber sensory neuropathy as the injury). Mot. at 34–36. He also notes the many record instances in which he displayed neuropathic symptoms (like tingling) "consistent with peripheral neuropathic injury." *Id.* at 38–39. To bulwark this contention, Petitioner briefly references some of the case study-oriented literature filed in the case. *Id.* at 39–42 (discussing Seneviratne; V. Martinez, et al., *Small Fibre Impairment Predicts Neuropathic Pain in Guillain-Barré syndrome*, 151 Pain 53–60 (2010), filed as Ex. 29, Tab B (ECF No. 26-3); G. Devigili, et al., *The Diagnostic Criteria for Small Fibre Neuropathy: From Symptoms to Neuropathology*, 131(7) Brain 1912–25 (2008), filed as Ex. 29, Tab C (ECF No. 26-4).

Moving on to the three prongs of the causation test established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005), Petitioner maintains that he has established that the Tdap vaccine could cause a generalized neuropathy, referencing what is known about the association between other vaccines and GBS. Mot. at 44–45. He invokes the kinds of mechanisms understood to be applicable in such circumstances (and referenced fleetingly in Dr. Morgan's reports), like molecular mimicry, arguing that they are comparably implicated in the pathogenesis of other polyneuropathies. *Id.* at 45. He further proposes that the "did cause" *Althen* prong has been met, emphasizing the number of instances in which Petitioner's treaters speculated as to a possible relationship between his symptoms and his June 2014 vaccination. *Id.* at 47–48. He also notes the absence of evidence of an alternative explanation for Petitioner's symptoms. *Id.* at 49. Finally, he posits that the two-day onset of armpit-swelling and pain was medically appropriate, referencing Dr. Morgan's opinion as well as Respondent's failure (via Dr. Cohen's report) to dispute this element of his claim. *Id.* at 49–51.

Respondent's Argument

Respondent seeks dismissal of Petitioner's claim. He begins by maintaining (contrary to Petitioner) that the Petitioner must in fact *establish* some injury to prevail, consistent with the Petition's allegations. Opp. at 11–13. But Petitioner, Respondent reasons, has attempted to define an inchoate kind of "peripheral polyneuropathy" based on the erroneous contention that there is a spectrum of GBS variants that would include a number of different neurologic symptoms of varying severity. *Id.* at 14–15. Petitioner otherwise maintains that he suffered from a small fiber sensory neuropathy, but that diagnosis does not fit the circumstances of this case. *Id.* at 15–18. Nor has Petitioner been successfully shown to suffer from GBS or some other broader variant. *Id.* at 18–24.

Respondent next reviews the extent to which Petitioner has satisfied the *Althen* prongs, finding his showing wanting. The first prong, he argues, cannot be satisfied based on the thin content of Dr. Morgan's reports, which rely heavily on the general invocation of the concept of molecular mimicry without independent substantiation, and failing to link it to either the injury Dr. Morgan most seemed to embrace (small fiber sensory neuropathy) or some other generalized neuropathy/GBS variant. Opp. at 24–27. Petitioner cannot establish that the Tdap vaccine "did cause" his alleged injury either, Respondent states, maintaining that the treater support in this case for an association between vaccine

and symptoms is inconsistent, tentative, or merely a historical recounting of sequence rather than a reliable causative opinion. *Id.* at 28–30. And the purported reasonableness of the timeframe in which Petitioner's symptoms first manifested is unsupported by reliable medical or scientific evidence. *Id.* at 31.

Petitioner's Reply

In a ten-page reply, Petitioner reiterated his earlier argument that his peripheral neuropathy was substantiated by the medical record, and a sufficiently-recognized injury in the Program to be grounds for an entitlement award. Reply at 2–4, 5–7. The fact that the precise nature of his injury had never been *diagnosed* was not fatal to the claim. *Id.* at 4–5. He also emphasized again the contention that GBS (or small fiber sensory neuropathies) were merely variants on the same spectrum under the umbrella "peripheral neuropathy." *Id.* at 8.

At the time of filing the reply, Petitioner also offered six additional items of literature. *See generally* ECF No. 34. Many of these merely discuss GBS or the known association between it and other vaccines—including those containing tetanus toxoid, like the Tdap vaccine Petitioner received. *See,* e.g., R. Bakshi, et al., *Guillain-Barré syndrome After Combined Tetanus-Diphtheria Toxoid Vaccination*, 147(2) J. Neurol. Sci. 201–02 (1997), filed as Ex. 32 (ECF No. 34-3) (single case report). Only one of the recently-filed articles was specific to small fiber neuropathies—a single case report involving a 14 year-old girl who developed a small fiber neuropathy within nine days of receipt of HPV vaccine—and although it discussed some evidence proposing other vaccines as similarly associated, it makes no mention of the Tdap vaccine as similarly suspect, and concludes that any association between vaccination and small fiber neuropathies "is not well defined." J. Kafaie, et al., *Small Fiber Neuropathy Following Vaccination*, 18 J. Clin. Neuromusc. Dis. 37–40 (2016), filed as Ex. 35 (ECF No. 34-6).

V. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time; or, (2) in the alternative, that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[13] In this case, Petitioner does not assert a Table claim.

[13] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. Each of the *Althen* prongs requires a different showing.

1. <u>*Althen* prong one</u>

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a

petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[14]

2. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (holding it was not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

3. *Althen* prong three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the

[14] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete"—i.e., presenting all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL

6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such oral testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under Daubert, the eliability of testimony is analyzed by considering:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial settings—e.g., the district courts. *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this

case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Resolution of Case Via Ruling on Record*

The parties have acquiesced to my determination that resolution of this case on the papers, rather than by holding a hearing, is appropriate under the circumstances. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Relevant Law

A. *Case Law Pertaining to Identification of Injury*

The parties contest whether establishing a specific injury is a prerequisite to an entitlement award. Respondent maintains (relying on the Federal Circuit's decision in *Broekelschen*) that a Vaccine Act claimant "*must* first establish that he suffered from the condition for which he seeks compensation *before* the Special Master can consider the evidence offered in support of whether the vaccine caused that injury." Opp. at 11, *citing Broekelschen*, 618 F.3d at 1346 (emphasis added). Petitioner counters that he need not do so, although in advancing this argument he inconsistently categorizes the alleged injury—sometimes defining it as a generalized peripheral neuropathy, other times (consistent with Dr. Morgan's report) squarely identifying it as a small fiber sensory neuropathy (within the overarching category of peripheral neuropathies). *Compare* Mot. at 22, 24, 40–41, 44–45, *with* First Morgan Rep. at 6.

The most reasonable reading of the proof offered in this case (particularly as set forth in Dr. Morgan's opinions) suggests that Petitioner ultimately relies on small fiber neuropathy as the proper diagnosis. As a result, Petitioner *has* offered a specific injury that can be analyzed based on the medical

record, consistent with *Broekelschen*. However, to the extent there remains any ambiguity about the nature of the alleged injury (and the concurrent possibility that Petitioner alternatively seeks to prove that he merely experienced an undefined kind of "peripheral neuropathy"), brief discussion of the issue is in order.

Respondent's position stems from a literal reading of Federal Circuit case law that somewhat ignores the context of those decisions. In *Broekelschen*, a petitioner maintained that the flu vaccine caused him to experience transverse myelitis (a common Program claim), while Respondent countered that the proper diagnosis was anterior spinal artery syndrome. *Broekelschen*, 618 F.3d at 1343. The distinctions between competing diagnoses was critical to the petitioner's chance of success, since (while both had overlapping symptoms) they were understood to have wholly different etiologies—meaning "the question of causation turns on which injury [petitioner] suffered." *Id.* at 1346. As a result, the Federal Circuit agreed that the special master deciding the case appropriately began his analysis with considering the injury before undergoing the *Althen* analysis. *Id.*

Respondent commits the same interpretive error in citing *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). There, a petitioner alleged three separate injuries, none of which Respondent accepted as accurate. *Lombardi*, 656 F.3d at 1352. The special master responsible for the case dismissed it for failure to establish injury, despite the fact that the claimant complained of a number of symptoms and test results that *could* be linked variously to the alleged injuries. *Id*. at 1345–46, 1349, 1355. In affirming, the Federal Circuit explained that because "the question of causation turn[s] on which injury the petitioner suffered," without an "injury," a causation analysis could not be performed. *Id.* at 1352. But there, as with *Broekelschen*, the inability to prove any of the alleged injuries was fatal to the claim. *See id.* (affirming decision of the special master dismissing the case after the special master found "no 'defined and recognized injury' was supported by the record . . . [and] dismissed the case without performing *Althen* analysis for causation of a non-existent injury.").

These cases mean that when there is a dispute as to a claimant's injury, the resolution of which is likely to be dispositive, it is appropriate for the special master to decide first whether preponderant evidence supports the petitioner's alleged injury. If the petitioner's causation theory is specific to the alleged injury (and relies on medical or scientific literature associating the vaccine in question with the injury), proving the injury actually occurred is vital—and the inability to do so means the claimant cannot meet the *Althen* prongs, obviating the need for that analysis. By contrast, a determination that the claimant suffered an injury *not* understood to be associated with a vaccine, and/or not likely an autoimmune-mediated process, will reduce or eliminate the possibility of the claim's success.

But it is not the case that a petitioner's claimed injury must *always* be one that is well-known or already clearly defined as a matter of medical science. This is inconsistent with the accepted view that special masters (who are judicial officers, not medical experts) are not charged with diagnosing a claimant's injury (even if they do assess whether *evidence* supports a particular diagnosis). This is especially true for "peripheral neuropathies" generally—a category which, as Petitioner accurately notes, has many sub-variants. Indeed, although there are very few cases in which the generalized injury

of "peripheral neuropathy" has been the basis for a successful Program claim, they do exist, as Petitioner has noted.[15]

Here (and in addition to the fact that Petitioner has articulated a specific injury), the causation theory by which a vaccine would potentially cause an unspecified peripheral neuropathy is not significantly distinguishable from that applicable to one of the more commonly-accepted variants. Accordingly, the mere fact that the Petitioner's alleged injury is more vague in nature is not necessarily dispositive of his claim. Respondent is, however, on firm ground in maintaining that proof of *some* injury (as opposed to simply symptoms) is required to prevail in a Vaccine Act case (since the absence of an injury at all will end the proceedings without any need to consider the *Althen* prongs). Opp. at 12, *citing Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364–65 (Fed. Cir. 2012) ("[i]f a special master can determine that a petitioner did not suffer [a vaccine injury], there is no reason why the special master should be required to undertake the separate (and frequently more difficult) [*Althen* analysis]"); *see also Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 262 (Fed. Cir. 2017) (symptoms alone could not satisfy petitioner's burden, because "a symptom or manifestation could indicate any number of different underlying injuries, each with its own pathology, making it impossible for the court to accurately determine causation") *aff'd* 696 F. App'x 497 (2017). These factors inform the analysis below.

B. *Small Fiber Sensory Neuropathy*

As both experts agree, a small fiber sensory neuropathy involves the small, mostly unmyelinated peripheral sensory nerves. First Morgan Rep. at 7–8; *see also A. Hovaguimian*, et al., *Dignosis and Treatment of Pain in Small Fiber Neuropathy*, 15(3) Curr. Pain Headache Rep. 193–200 (2012), filed as Tab E to Ex. 27 (ECF No. 20-1) ("Hovaguimian"), at 194; *Shaw v. Sec'y of Health & Human Servs.*, No. 01-707V, 2013 WL 2897425, at *12 (Fed. Cl. Spec. Mstr. May 24, 2013) (Hep B vaccine caused small fiber neuropathy). The injury features symptoms of chronic pain and itching, coupled with sensory impairment, among other things. Hovaguimian at 194; *Jones v. Sec'y of Health & Human Servs.,* No. 15-1239V, 2018 WL 7139212, at *5 (Fed. Cl. Spec. Mstr. Dec. 21, 2018) (denying entitlement); Cohen Rep. at 4. Small fiber sensory neuropathies typically do *not* involve other abnormal physical or neurologic symptoms, however, thus distinguishing them from many common peripheral neuropathies like GBS (although it can from an etiologic perspective be *associated* with them—and arguably, as some of Petitioner's literature suggests, constitute a secondary feature of an initial peripheral neuropathy like GBS). Hovaguimian at 194, 195.

Small fiber sensory neuropathies are difficult to diagnose, and a skin biopsy is considered critical in confirming the diagnosis. *See* Hovaguimian at 195–96; *Jones*, 2018 WL 7139212, at *5; *Shaw*, 2013 WL 2897425, at *12, 13; *see also L.A.M. v. Sec'y of Health & Human Servs.,* No. 11-852V, 2017 WL

[15] *See* Reply at 2 n.3. Of course, all of these cases involve *settled* cases, rather than reasoned decisions, and therefore do not set forth the kind of precise circumstances that a claimant alleging such a nonspecific injury must meet. I also note that each of the four cited decisions settled for less than $40,000, suggesting at a minimum that the degree of injury involved was relatively slight, at least in comparison to some of the more drastic injuries at issue in the Program.

527576, at *45 (Fed. Cl. Spec. Mstr. Jan. 31, 2017). However, cases alleging a small fiber sensory neuropathy injury have succeeded even where the skin biopsy was inconclusive, *as long as* reliable treater support for the diagnosis was evident. *See, e.g.*, *Shaw*, 2013 WL 2897425, at *14–15. EMG and NCS studies, by contrast, are less revealing in establishing this diagnosis, since such testing has more relevance to *myelinated*, larger nerve fiber function, and thus may return normal results even in the existence of a "pure" small fiber neuropathy. Hovaguimian at 196–97.

II. The Record Does Not Support Petitioner's Contention that He Experienced a Small Fiber Sensory Neuropathy

The medical record does not corroborate Dr. Morgan's opinion that Petitioner's injury was a small fiber sensory neuropathy. Most significantly, Petitioner has *never* received such a diagnosis from virtually any of his treaters—something deemed significant in other cases where testing did not otherwise support the proposed injury. *Shaw*, 2013 WL 2897425, at *14–15. He also never had a skin biopsy (which even Dr. Morgan allowed was, as Dr. Cohen put it, the "gold standard" for confirming a suspected case of small fiber sensory neuropathy (Second Morgan Rep. at 4))—meaning not only that a critical element of proof that could confirm the proposed diagnosis is missing, but also that none of Petitioner's treaters even considered conducting such a test, thus further diminishing the likelihood that that small fiber sensory neuropathy best explains Petitioner's condition. Nor did the other testing and numerous examinations that Petitioner experienced over the course of his treatment corroborate such a diagnosis.

Arguably, the records from the period of Dr. Martinez's treatment of Petitioner in the late summer-early fall of 2014 provide the best support for the contention that Petitioner had experienced some kind of "sensory demyelinating neuropathy," as Dr. Martinez put it. Ex. 4 at 21. However, the overall treatment record beyond this timeframe must be considered in evaluating Petitioner's entitlement to damages. Here, the treatment record, when evaluated in its entirety, does not corroborate Dr. Martinez's early assessments. Not only did *no* other subsequent treater extend or refine this tentative diagnosis to something like a small fiber sensory neuropathy, but (as Dr. Cohen observed in his expert report), subsequent, more-comprehensive testing at UC-Irvine, performed by a neurology specialist, was inconsistent with Dr. Martinez's evaluation. Cohen rep. at 4–5.

Further, Dr. Martinez's speculation as to Petitioner's condition at the time is in some respects not even consistent with what is known about a small fiber neuropathy. Small fiber neuropathy involves two types of small nerve fibers: (1) Alpha Delta fibers, which are thinly myelinated; and (2) C Fibers, which are unmyelinated. *See* Hovaguimian; *see also Shaw*, 2013 WL 2897425, at *12. On one hand, small fiber neuropathy that involves the Alpha Delta Fibers is associated with "shooting pain in the limbs with throbbing." *See Shaw*, 2013 WL 2897425, at *12. On the other hand, small fiber neuropathy that involves the C fibers is associated with "'[s]low pain and temperature ([d]ull, burning, poorly localized pain).'" *See id.* (alterations in original) (quoting J. Tavee, et al., *Small Fiber Neuropathy: A Burning Problem.*, 76(5) Clev. Clin. J. Med. 297, 298 (May 2009)). Here, Petitioner's symptoms are described as "tingling" and "numbness." *See, e.g.*, Ex. 2 at 24. This is more in line with small fiber neuropathy associated with the unmyelinated C fibers, and hence is likely not demyelinating in the first

place, as Dr. Martinez initially proposed. Nor is small fiber neuropathy known to occur *only* in the wake of a demyelinating autoimmune condition—and where it arguably does (as some of Petitioner's literature, like Seneviratne, suggests), this medical record does not establish that Petitioner experienced any other known demyelinating injury, like GBS, *before* developing small fiber neuropathy on a secondary level.

The experts disagree as to the proper diagnosis, but ultimately Dr. Morgan's opinion was not sufficiently persuasive to turn the tide on this point in Petitioner's favor. Dr. Morgan employed conclusory reasoning, and did not credibly explain why the overall record best supports the conclusion that Petitioner had experienced a small fiber sensory neuropathy. In addition, although Dr. Morgan had the professional credentials necessary to opine on neurologic issues generally, he lacks demonstrated specific expertise in the kind of injuries at issue in this case to give his opinion added heft. Dr. Cohen, by contrast, succinctly reviewed all of the symptomatic clinical or lab indicia relevant to a diagnosis of small fiber sensory neuropathy, and in so doing persuasively demonstrated why the record does not support such a diagnosis. Cohen Rep. at 4.

III. Petitioner's Non-Specific Symptoms are not a Basis for Entitlement Even if They Overlap With Known Symptoms of Other Peripheral Neuropathies

Although Dr. Morgan's reports clearly reveal his embrace of small fiber sensory neuropathy as the proper diagnosis for Petitioner's injury, the briefing for the ruling on the record motion is equivocal, and sometimes characterizes his injury as a generalized peripheral neuropathy. *See,* e.g., Mot. at 34. But even if Petitioner had solely proposed peripheral neuropathy as the likely injury, this contention would have two substantive deficiencies.

First, Petitioner has not persuasively established that there *is* a cognizable, nonspecific "peripheral neuropathy" vaccine injury that has some, but not all, features of other kinds of commonly-recognized injuries within that spectrum. While some of Petitioner's literature (such as Seneviratne) allows that a sensory neuropathy could be a secondary effect of a primary demyelinating condition like GBS, the record established (and Dr. Morgan admitted) that Petitioner never experienced such a primary injury. To some extent, Petitioner's embrace of a vague overarching category to describe his injury seems to reflect an effort to dodge those clinical indicia he cannot establish. Thus, to give one example, it does not matter under Petitioner's theory that he cannot demonstrate that he suffered from the "classic" form of GBS, as Dr. Morgan concedes, because Petitioner's injury happens to fall *elsewhere* on the purported spectrum. Second Morgan Rep. at 4–5. In so arguing, Petitioner may evade his inability to establish one particular form of peripheral neuropathy—but he cannot evade them all while also proposing how similar his purported injury was.

Second, even if I were to find that a claimant *could* prevail in an entitlement case by establishing that he suffered from some generalized kind of mild peripheral neuropathy that otherwise did not meet all of the criteria for the most commonly-recognized subtypes (or even for a small fiber sensory neuropathy, which *is* recognized), his argument *here* relies more on the symptoms he experienced than some foundational injury that produced those symptoms. He references a number of complained-of

symptoms over a long period of time and for which he sought treatment, but which never resulted in a convincing diagnosis supported by preponderant evidence. But he does not demonstrate the underlying injury that would cause such a chronic process, lasting several years and featuring a stuttering progression of symptoms, many of which were not corroborated by testing or not deemed to reflect underlying neurologic injury. And Dr. Morgan did not persuasively establish a catch-all kind of peripheral neurologic injury that would lack critical features of the identified, more commonly-understood injuries, but otherwise stand on its own.

IV. Petitioner Has Not Satisfied the *Althen* Prongs with Preponderant Evidence

Because Petitioner cannot establish preponderant evidence in favor of any vaccine injury, there is no need to undergo a full *Althen* analysis. *Hibbard*, 698 F.3d at 1364–65. However, even a cursory review of the three prongs of the test reveals that Petitioner cannot meet his burden of proof.

This case features a conflict between the second, "did cause" prong and the first and third prongs. Dr. Morgan's expert report provides thin support for a causal theory linking the Tdap vaccine to small fiber sensory neuropathy, relying too heavily on the blanket invocation of mechanisms like molecular mimicry that have only been persuasively related to *other* kinds of neuropathies, like GBS, or proposing an association between GBS and small fiber sensory neuropathy that does not appear to have (yet) been reliably established. However, the theory has found success in other cases, and/or for other vaccines. *See,* e.g., *Jones,* 2018 WL 7139212, at *13–14 (finding that petitioner succeeded in establishing the Tdap vaccine could cause small fiber neuropathy); *Doe v. Sec'y of Health & Human Servs.,* No. [redacted], 2007 WL 3120297, at *7–8 (Fed. Cl. Spec. Mstr. Oct. 18, 2007) (finding that flu vaccine can cause small fiber neuropathy).

Such cases are not dispositive herein, but they are rooted in persuasive reasoning that is worthy of my notice. The evidence presented on this first prong of the *Althen* test is thus close enough to find it *barely* preponderates in Petitioner's favor. In addition, even if the initial symptoms Petitioner reported were deemed transient, he began reporting symptoms that could reasonably deemed neurologic in origin within two weeks of vaccination—a reasonable timeframe for an autoimmune process to have begun with a neuropathic impact. Accordingly, the third *Althen* prong is arguably established as well.

However, the evidence *does not* preponderate in favor of the conclusion that the Tdap vaccine *did* cause any injury to Petitioner under the facts of this case. First, and as discussed above, the record does not support the conclusion that Petitioner ever experienced a small fiber sensory neuropathy, and Petitioner's fallback contention that he suffered from a generalized peripheral neuropathy finds little support in the record or the medical science as offered in this case. Second, the medical record does not allow for the conclusion that (beyond a possible immediate but transient vaccine reaction, which is not fully corroborated by evidence beyond Petitioner's personal statements) the Tdap vaccine was anything more than temporally associated with his subsequent symptoms. The overall testing and examinations Petitioner received do not establish that he experienced an autoimmune process causing injury (expressed by the symptoms of which he complained), nor did the majority of treaters ultimately link

the vaccine to his symptoms. And Dr. Martinez's diagnostic speculation was not ultimately substantiated by the subsequent treatment history.

As a result, even if Petitioner succeeded in meeting his burden of proof as to the first and third *Althen* prongs, he did not satisfy the second, and therefore did not carry his overall preponderant burden of proof.

CONCLUSION

Accordingly, and for the aforementioned reasons, I DENY entitlement in this case. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[16]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[16] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.